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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,341	07/06/2005	Miroslav Veverka	262999US0PCT	3636

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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

NOTIFICATION DATE	DELIVERY MODE
12/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/525,341	VEVERKA ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 22, 2008 have been entered and considered carefully.

Claim 7, has been canceled. Currently amended claims 1-6 and newly added claims 8-12 are pending.

2. A certified translation of the priority document was filed by applicants dated Aug. 22, 2008.

Please note that 35 USC 119 stated that:

> "(a)An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing."

In the instant case, the priority document is not the *same* invention as the currently submitted application. Please note that examples 5-6 and figures 4-5 of the instant application is **not** found in the priority document and the priority benefit cannot be granted. Application date for the instant application is the PCT application date Aug. 28, 2003.

3. The rejection of claim 7 under 102(b) or (a) over Bardore '265 or Bousquet '210 is dropped in view of the cancellation of the claim.

4. The rejection of claims 1-7 under 35 USC 103(a) over Bardor or Bousquet in view of Liftshitz supplemented with Mukarram is dropped in view of the amendment and the following new grounds of rejections.

5. The rejection of claims 1-6 under 35 USC 112 first paragraph is maintained for reason of record and now also applicable to the newly added claims 8-12.

Applicants presented that the art of record offered very complexed scientific measurements in polymorphic crystalline forms of a product. The examiner should be confused. Indeed, the polymorphic crystalline form art with complexed and specific scientific measurements is the nature of such field. The provision of such complexed and confusing factual evidence from the prior art has indicated the extremely burdensome effort made by the examiner in "proof of initial burden" to evidence the difficulty of the PTO in making documentation, analysis and comparisons of the different polymorphic products described and claimed in the field. The burden is at applicants' to provide the office with clear, precise and convincing evidence what is the "product" being made, how is the steps and process of making demarcated from the prior art and what is the novelty or unobviousness critical from the prior art and limited to the operability of the claims. The mere allegation that there is overwhelming evidence supporting applicants' claims, when the specification was not identical to the priority documents, when there is overwhelming confusing prior art made of record, does not obviate the rejection. Factual support must be provided to indicate whether identical or different products were made, and under what specific operability was the products made and such limitation commensurate to the operability must be found in the claims.

6. In view of the amendment, the following new grounds of rejections are made:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lifshitz-Liron et al. US 7,074,928 or Mukarram et al. WO2005/012300.

See Lifshitz-Liron '928 col. 20-21, examples 18-25 wherein hydrogen sulphate (alpha S) of the alpha-(2-chlorophenyl)-6,7-dihydro-thieno[3,2-c]pyridine-5(4H)-acetic acid methyl ester (clopidogrel hydrogen sulphate) was crystallized into form I with methanol or

ethanol, thus anticipated the scope of the claims when the process employed *primary, secondary and tertiary C1-C5 alcohols*.

See Mukarram et al. '300 see page 5, example (b) wherein hydrogen sulphate (alpha S) of the alpha-(2-chlorophenyl)-6,7-dihydro-thieno[3,2-c]pyridine-5(4H)-acetic acid methyl ester (clopidogrel hydrogen sulphate) was crystallized into form I with ethylacetate thus anticipated the scope of the claims when the process employed esters of C1-C5 alcohols and C1-4 carboxylic acids.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lifshitz-Liron et al. US 7,074,928 or Mukarram et al. WO2005/012300 in view of each other or in view of Bardore et al. US 4,847,265 or Bousquet et al. US 6,429,210.

Determination of the scope and content of the prior art (MPEP §2141.01)

Lifshitz-Liron '928 or Mukarram et al. '300 disclosed anticipatory process of making form I of hydrogen sulphate(alpha S) of the alpha-(2-chlorophenyl)-6,7-dihydro-thieno[3,2-c]pyridine-5(4H)-acetic acidmethyl ester (clopidogrel hydrogen sulphate) using alcohol or ester.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the references and the instant claims is that "mixtures thereof" was not employed. Lifshitz-Liron '928 demonstrated alcohol and taught that ether will be

operable in transforming hydrogen sulphate(alpha S) of the alpha-(2-chlorophenyl)-6,7-dihydro-thieno[3,2-c]pyridine-5(4H)-acetic acidmethyl ester (clopidogrel hydrogen sulphate) into form I (col. 7-8 paragraph bridging) as well as crystallizing from alcohol (examples 18-25 col. 20-21). Mukarram '300 demonstrated crystallization from ester produced form I, Bardore et al. US 4,847,265 or Bousquet et al. US 6,429,210 demonstrated that crystallization from acetone produced form I.

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the above references would be motivated to carry out the crystalline process in mixtures of solvents since all such solvents can produce form I. Changing parameters of experimental conditions in a chemical process is routine chemical manipulation. In the instant case especially variations of conditions disclosed in all the above references and particually taught by Mukarrum '300 disclosed that variation of solvents will produce product differ by degree of purity (p.3), thus, one would be motivated to vary conditions and solvents with the expectation that a desirable degree of purity in product will be obtained.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –.
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-6, 8-9 are rejected under 35 U.S.C. 102(g) as being anticipated by Mukarram et al. US 2008/0051581.

See claims 20-29.

9. Applicants' amendment necessitated the new grounds of rejections.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 8, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625